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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/269,903 05/06/99 WATTS

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EXAMINER

WILLIAMS, P

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 08/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/269,903	WATTS, PETER JAMES	
	Examiner	Art Unit	
	Pernell V. Williams	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) Responsive to communication(s) filed on 25 May 2000.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-28 is/are pending in the application.
 - 4a) Of the above claim(s) 18 and 20 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-15, 17, 19, 21, 22 and 24-28 is/are rejected.
- 7) Claim(s) 16 and 23 is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - a) All b) Some * c) None of the CERTIFIED copies of the priority documents have been:
 1. received.
 2. received in Application No. (Series Code / Serial Number) _____.
 3. received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9
- 18) Interview Summary (PTO-413) Paper No(s) _____
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other: _____

DETAILED ACTION

This paper immediately follows paper numbers 9 and 10, both entered into the instant application 25 May 2000. The amendments submitted 25 May 2000 have been entered, which amend claim 16 and adds claims 23-28. **Claims 1-17, 19, and 21-28 are pending; claims 18 and 20 have been canceled.**

Information Disclosure Statement

The information disclosure statement, submitted 25 May 2000, has been reviewed. However, in contrast to the contents of the accompanying letter which states that **four** references were disclosed, only **three** references have been set forth.

Response to Arguments

Claim Objections

Applicant's arguments filed 25 May 2000 have been fully considered but they are not persuasive. The objection to claim 16 set forth in the office action mailed 21 January 2000 is maintained for the reasons of record. In addition, newly added claim 23 is also objected to for the reasons of record, in addition to the reasons which follow.

1. It was well known to the artisan of ordinary skill in this art at the time the invention was made that in order to make an salt out of the combination of a weak acid and an alkali metal, interaction of said acid and said metal must take place in solution.

Any steps using said salt would therefore require obtaining said salt from a solution: hence, claim 16 as amended is not seen to further limit the parent claim 15.

2. Additionally, the methods by which said salt is made is not seen to be of patentable import on the process of claim 16. Claim 15, from which claim 16 depends, requires the use of a salt. The manner in which said salt is prepared is not seen to further limit the process of claim 15. The amendment or claim 16 is not seen to augment the distinction between the formation or making of a salt in claims 15 and 16.

3. Likewise, newly added claim 23 is not seen to further limit claim 15. Claim 23 is noted to set forth steps which comprise recovery of the solid salt sometime before coating or the inner cores. The instant claim is not seen to clearly delimit use of said salt as a solid, and hence is not seen to further limit the method steps of claim 15 from which claim 23 depends.

Claim Rejections - 35 USC § 103

4. Applicant's arguments filed 25 May 2000 have been fully considered but they are not persuasive. Regarding the rejection under 35 U.S.C. § 103(a) of claims 1-17, 19, and 21-22, said rejection is maintained for the reasons of record. Newly added claims 23-28 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 5,376,384 (Eichel *et al.*), and further in view of U.S. Patent 5,180,832 (Freyne *et al.*) for the reasons of record and the reasons set forth below.

5. Applicant argues that comparisons of Eichel *et al.* are not drawn to compositions designed to reach the terminal ileum or colon. However, Eichel *et al.* sets forth that the

compositions set forth therein are intended to delay drug release for up to 10 hours after ingestion (column 3 lines 55-62), which is seen to be sufficient for the prior art formulation to reach the terminal ileum or colon. It is obvious to delay release of a drug and, upon release, require sustained delivery.

6. Thickness is taught in Eichel to be directly correlative to the time of release. Modification of delayed release formulations by the skilled artisan in this field is routine, wherein fractions of immediate and delayed sustained-release drugs are disclosed (column 6 lines 29-51). That Eichel *et al.* discloses the inclusion of immediate-release salts is seen to include the incorporation of aqueous compositions such as the formulation type set forth in Freyne *et al.* patent, drawn to alkali metal salts of drugs for oral administration (text bridging column 5 line 58 with column 6 line 20).

Applicant has not met the burden of obviating the *prima facie* rejection under 35 U.S.C. § 103(a) of record. Taking the phrase "adapted to prevent release of drug until the composition reaches the terminal ileum or colon" as a limitation describing property of applicants' claimed delayed release composition, reference's delayed sustained release composition is inherently one which has that property in same sense as applicants' claimed sustained release composition, as set forth on page 9 lines 11-24 of the specification of the instant application. Therefore, recitation of that property in the instant claims does not distinguish said claims over the prior art patents. The prior art disclosure of the property shows that the delayed sustained release is not a newly discovered one. The instant claims are not sufficient to distinguish over a reference setting forth that property.

7. It is noted that the arguments submitted 25 May 2000 are silent with regard to the rejection of the method claims. The rejection is noted on page 4 of the instant response, yet the applicant's reproof has failed to fully respond to the rejection of claims 15-19.

8. Claims 1-17, 19, and 21-28 are not allowed at this time.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pernell V. Williams, whose telephone number is (703) 308-4645. The examiner can normally be reached from 8AM to 4:30PM Monday to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, Examiner James O. Wilson may be reached at (703) 308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



James O. Wilson
Primary Examiner
Art Unit 1623



PVW
August 25, 2000